Catholic Women's League Australia – New South Wales Inc.

ABN 27 783 418 042

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Submission to:

The Senate Community Affairs Committee –
Inquiry into Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005.

Submission from:

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Catholic Women's League Australia, NSW Inc (CWLA, NSW Inc) is a State wide, non-government and non profit organization of women who believe in "promoting the spiritual, cultural, intellectual and social development of women" and who demonstrate a commitment to the dignity of women, the value of all human life and the maintenance of a caring and compassionate society.

Part A.
This bill is intended to remove responsibility for approval for RU486 from the Minister for Health and Ageing and to provide responsibility for approval of RU486 to the Therapeutic Goods Administration.

It is our opinion that there is no need remove responsibility for approval for RU486 from the Minister for Health and Ageing and to provide responsibility for approval of RU486 to the Therapeutic Goods Administration.

Sections from Schedule 1—Amendment of the Therapeutic Goods Act 1989 for which repeal is requested

1 Subsection 3(1) (definition of *restricted goods*)

2 Section 6AA

3 Section 6AB

4 Section 23AA

5 Subsection 57(9)

The definition of 'restricted goods' is clear and leaves a possibility for uses of this type of substance for uses other than abortion in the future. In fact there is evidence that this drug is already being used in Australia.

Section 6AA does not need to be changed. There is already the option for a potential prescriber/researcher to make a request to the Minister for approval of the import any restricted goods into Australia. Information in the press indicates that an Obstetrician/Gynaecologist from Queensland has already done so. These sections should remain as unless the previous sections are changed they remain irrelevant. Notice is taken of a previous lack of consultation and dialogue within the Department (1994)

Although The TGA is specifically charged with identifying, assessing and evaluating the risks posed by therapeutic goods that come into Australia, applying any measures necessary for treating the risks posed, and monitoring and reviewing the risks over time mistakes have been made in the past where drugs thought to be safe or without major risk have needed to be recalled. This recall however only occurs after considerable time has elapsed and complications to the users of the drugs.

Part B

The safety of the drug and thus the health risks for the woman user remains in question.

Of course the health risk to the growing baby is supreme and final in 98% of cases.

The drug Mifepristone (RU486) is a progesterone receptor antagonist and abortifacient, but was originally investigated for its antiglucocorticoid effects as a potential treatment for Cushing's syndrome. The information about the safety of RU486, (mifepristone, Mifeprex®, Mifegyne) is confusing. "In the US, postmarketing reports from 2000 through to the end of October 2004, have recorded 676 adverse events following 350,000 applications, ranging from minor symptoms such as nausea and dizziness to more serious adverse events, including hospitalization and death.

1 3 women have died
2 17 women have had ectopic pregnancies
3 72 women have experienced blood loss requiring transfusions
4 7 women have had serious bacterial infections

"FDA and Danco Laboratories have received reports of serious bacterial infection, bleeding, ectopic pregnancies that have ruptured, and death, including another death from sepsis that was recently reported to FDA. These reports have led to the revision of the black box labelling." [FDA Statement, Nov 2004]

Danco Laboratories announced on July 18th 2005, that as a result of information about adverse events that it is modifying the labeling for Mifeprex® to include updated safety information. The news release stated in part,

> *"Danco is committed to providing updated safety information about this early option for women. We will be sending a Dear Doctor Letter soon to all providers of Mifeprex®, as well as to all emergency room directors, to ensure that they are aware of this new information," said Cynthia Summers, Dr.P.H., Director of Marketing and Public Affairs, Danco Labs. "Danco is working with the FDA to update the Mifeprex® labeling, Medication Guide and Patient Agreement with this information."*

The company covered themselves by the statement, "Childbirth, menstruation and abortion, whether spontaneous, surgical or medical, all create conditions that can result in serious and sometimes fatal infection, and there is no evidence that Mifeprex® and misoprostol present a special risk of infection."

They do however warn users, "Women who are undergoing a medical abortion with the Mifeprex® and misoprostol regimen should contact their provider or an emergency room right away if they experience abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting or diarrhea), with or without fever, more than 24 hours after taking misoprostol."

Health Canada (who does not permit use of RU486) has circulated information about some deleterious effects of this drug in their Canadian Adverse Reaction Newsletter. (Available on line). The newletter continues - Widely used in Europe and the United States, it is not licensed for use in Canada. According to the FDA-approved protocol, 600 mg of mifepristone is taken orally within 49 days after
the start of a woman's last menstrual period. Two days later 400 mg of the prostaglandin misoprostol is taken orally .... if the pregnancy has not already ended. Ten days later the woman is followed up clinically, often with ultrasonography, to confirm termination of her pregnancy. Complete medical abortion occurs in about 92% of women taking the regimen, but 5%–8% require a surgical procedure because of incomplete abortion, excessive bleeding or continuing pregnancy. Common adverse effects of the regimen include abdominal

cramping and vaginal bleeding, headache, nausea and vomiting, and diarrhea. Rare but fatal cases of ruptured ectopic pregnancy have occurred. In most cases the uterus will be emptied within 24 hours, but in about 35 percent of cases, it can take several days or weeks. Pain medication is necessary to ease the pain of the cramps that can be severe, and occur when the pregnancy tissue comes out of the uterus. Users of this drug have reported severe pain, significant haemorrhage leading to need for resuscitation and/or ongoing anaemia.

"Because RU 486 is administered with prostaglandins, its effect on the immune system must be studied further. When used in organ transplant procedures, much smaller doses of prostaglandins than are administered with RU 486 inhibit the immune response" (Klein, Raymond & Dumble) This situation could further impair the health and well being of the woman who for whatever reason has a compromised immune system.
"Pro-choice, not pro-woman, has become the slogan for groups acting to protect abortion rights for women in western countries." (Klein, Raymond & Dumble) The question remains about whether or not RU486 will increase choices or options women have? Often abortion is the only choice they are offered by counselors, pregnancy help groups and abortion clinic staff. There is a danger in women making choices without complete information including the "right to choose" to continue the pregnancy with support. Because of prevailing social situations women can be frightened, vulnerable, and forced into abortion, by parents, partners and husbands and or ill informed friends.

Many critics of the pill say it makes abortion easier and worry that the pill will be used as a form of birth control. A report by the Spanish bioethicist, Herranz, discusses the use of RU-486 as a contraceptive, stating: "Women would no longer have to worry themselves about whether they have conceived or not. Each month they would proceed to clean out their uterus chemically." The report refers to RU-486 as "a technical step forward in an area that did not need it." It says, "The abortion pill favors a woman's privacy and secret, but it condemns her to solitude." (1991).

Australians spoke of abortion as a last resort in the report of research undertaken in 2004. The respondents are concerned about the physical health of women who desire termination, and although supportive of legal access to abortion, Australians are deeply ambivalent about the morality of abortion. Apart from 'hard cases' involving a danger to the mother's health or foetal disability, fewer than 1 in 4 thinks abortion is morally justified (Fleming & Ewing 2005).

CWLA, NSW Inc members are pro woman and believe that every woman should have a choice over her own sexual health but that that choice is made within the context of education, options, societal support and control over their sexuality in general. Part of our mission is to assist women in those situations in which they feel compromised , to get them the help they need to keep their babies, remain healthy. Whichever way it is done, medically or surgically abortion is a sad reflection that as a society we are not addressing the real needs of women.

It is our view that it is not necessary to remove responsibility for approval for RU486 from the Minister for Health and Ageing and to provide responsibility for approval of RU486 to the Therapeutic Goods Administration.